

SAFETY DATA SHEETS

This SDS packet was issued with item:

078937801

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078933555 078936565



SAFETY DATA SHEET – PIROXICAM CAPSULES USP

1. IDENTIFICATION

Product Identifier : Piroxicam Capsules USP 10 mg & 20 mg

Active Ingredient : Piroxicam

Synonyms : Piroxicam

Chemical Name :

- 4-Hydroxy-2-methyl-*N*-(pyridin-2-yl)-2*H*-1,2-benzothiazine-3-carboxamide 1,1- dioxide
- 4-Hydroxy-2-methyl-*N*-2-pyridyl-2*H*-1,2-benzothiazine-3-carboxamide 1,1- dioxide
- 3,4-Dihydro-2-methyl-4-oxo-*N*-2-pyridyl-2*H*-1,2-benzothiazine-3-carboxamide-1,1-dioxide
- 2*H*-1,2-Benzothiazine-3-carboxamide, 4- hydroxyl-2-methyl-*N*-2-pyridinyl-1,1-dioxide

Molecular Formula : C₁₅H₁₃N₃O₄S **Molecular Weight** : 331.35

CAS Number : 36322-90-4

Recommended Use : Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

Recommended restrictions : None known

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2. HAZARD(S) IDENTIFICATION

Appearance

: Piroxicam Capsules USP 10mg : Maroon Opaque cap with imprinting 'PR' and Blue Opaque body with imprinting '10', size "4" hard gelatin capsules filled with off-white to light tan or light yellow powder.

Piroxicam Capsules USP 20mg : Maroon Opaque cap with imprinting 'PR' and maroon Opaque body with imprinting '20', size "2" hard gelatin capsules filled with off-white to light tan or light yellow powder

Classification of the substance or Mixture

GHS – Classification

: Reproductive Toxicity – Category 1A
Specific target organ systemic toxicity (repeated exposure) – Category 1

Label Elements

Signal word

: Danger

Hazard Statements

:

- May damage the unborn child.
- Causes damage to organs through prolonged or repeated exposure if swallowed.

Precautionary Statements

:

- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Use personal protective equipment as required.
- If exposed or concerned: Get medical attention/advice.
- Do not breathe dust/fume/gas/mist/vapors/spray.
- Wash hands thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- If exposed, call a POISON CENTRE or doctor/physician.
- Disposal of contents/containers in accordance with all local and national regulations.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.



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3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS Number	%
Piroxicam	36322-90-4	6.67
Lactose Monohydrate	64044-51-5	*
Starch Pregelatinised	9005-25-8	*
Sodium Lauryl Sulfate	151-21-3	*
Magnesium Stearate	557-04-0	*
Hard gelatin capsules	Mixture	*

*- Proprietary information

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Description of First Aid measures:

Eye contact	:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin contact	:	Remove contaminated clothing. Flush area with large amounts of water for at least 15 minutes. Use soap. Seek medical attention. Wash clothes before reuse.
Ingestion	:	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person.



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Inhalation : Do not induce vomiting unless directed to do so by Medical personnel.
: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek medical attention immediately.

Most important symptoms and effects, both acute and delayed

Symptoms and Effects of Exposure : Mentioned under section 2: Hazards Identification and section 11: Toxicological Information.

Medical conditions aggravated by exposure : None known

Indication of the immediate medical attention and special treatment needed

Notes to Physician : None

5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media : Use alcohol-resistant foam, carbon dioxide, dry chemical supply.

Unsuitable Extinguishing Media : A solid water stream may be inefficient.

Hazardous combustion products : Formation of toxic gases is possible during heating or Fire.

Fire/Explosion Hazards : Fine particles (such as dust and mists) may fuel fires/ Explosions.

Advice for Fire fighters : During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.



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6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective Equipment :
and Emergency Procedures : Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
- Environmental precautions : Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
- Measures for Cleaning/collecting : Collect the spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
- Additional consideration for large spills : Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

- Precautions for safe Handling : Minimize dust generation and accumulation. If capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal equipment. Wash hands thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and



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waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage conditions : Store as directed by product packaging.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering controls : General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination level is below the exposure limits.

Personal protective equipment

Hands : Wear protective gloves when working with large quantities.

Eyes : Wear safety glasses or goggles if eye contact is possible.

Skin : Wear protective clothing when working with large quantities.

Respiratory protection : If the applicable occupational exposure limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : Hard gelatin Capsule

Odor : No data available



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Odor threshold	: No data available
Color	: Maroon/Blue(10mg) Maroon/Maroon (20mg)
Molecular weight	: Mixture
Molecular formula	: Mixture
Solvent Solubility	: No data available
Water Solubility	: No data available
pH	: No data available
Melting/Freezing Point (°C)	: No data available
Boiling Point (°C)	: No data available
Partition Coefficient: (Method, pH, Endpoint, Value)	
Piroxicam	: No data available
Lactose NF,monohydrate	: No data available
Magnesium Stearate	: No data available
Sodium lauryl sulfate	: No data available
Hard gelatin capsules	: No data available
Starch	: No data available
Decomposition temperature (°C)	: No data available
Evaporation Rate (Gram/s)	: No data available
Vapor Pressure (kPa)	: No data available



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Vapor Density(g/ml) : No data available

Relative Density : No data available

Viscosity : No data available

Flammability:

Auto ignition Temperature (solid) (°C) : No data available

Flammability (Solids) : No data available

Flash Point (Liquid) (°C) : No data available

Upper Explosive Limits (Liquid) (% by Vol) : No data available

Lower Explosive Limits (Liquid) (% by Vol) : No data available

Polymerization : Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability : Stable under normal conditions of use.

Conditions to avoid : Fine particles (dust and mists) may fuel fires/explosions.

Incompatible Materials : Keep away from Strong oxidizers.

Polymerization : Will not occur

11. TOXICOLOGICAL INFORMATION

Short term : Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.



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Known Clinical Effects

: Ingestion of this material may cause serious gastrointestinal toxicity such as bleeding, ulceration and perforation and kidney toxicity. Other piroxicam treatment related effects include headache, dizziness, blurred vision, ringing in the ears, skin rashes and itching, swelling and liver effects.

Acute Toxicity:

Piroxicam

: Mouse Oral LD50 360 mg/kg

Rat Oral LD50 270mg/kg

Mouse IP LD50 360mg/kg

Rat IP LD50 220mg/kg

Dog Oral LD50 > 700mg/kg

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation/Sensitization:

Piroxicam

Eye Irritation

: Rabbit Non-irritating

Skin irritation

: Rabbit Non-irritating

Repeated Dose Toxicity:

Piroxicam

: 3 Month(s) Rat Oral 5mg/kg/day NOAEL
Gastrointestinal system

3 Month(s) Monkey Oral 2.5mg/kg/day NOAEL
Gastrointestinal system

18 Month(s) Rat Oral 1mg/kg/day NOAEL



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Gastrointestinal system, Kidney

Reproduction & Development Toxicity

- Piroxicam : Reproductive & Fertility Rat Oral 10 mg/kg/day
NOAEL No effects at maximum dose
- Pre-/Postnatal Development Rat Oral 2mg/kg/day
LOAEL Developmental toxicity
- Fertility and Embryonic Development Rat Oral 10
mg/kg/day NOAEL No effects at maximum dose, Not
Teratogenic
- Fertility and Embryonic Development Rabbit Oral 10
mg/kg/day NOAEL No effects at maximum dose, Not
Teratogenic

Genetic Toxicity

- Piroxicam : In Vitro Bacterial Mutagenicity Salmonella, E.coli
Negative
- In vitro Cytogenetics Human Lymphocytes Negative

Carcinogenicity

- Piroxicam : 2 year(s) Rat Oral 1mg/kg/day NOAEL Not
carcinogenic
- Carcinogen status : None of the components of this formulation are listed as
a carcinogen by IARC, NTP or OSHA

12. ECOLOGICAL INFORMATION

- Environmental Overview : The environmental characteristics of this mixture
have not been fully evaluated. Releases to the
environment should be avoided.



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13. DISPOSAL CONSIDERATIONS

Waste treatment methods : Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water.

14. TRANSPORTATION INFORMATION

Not regulated for transport (all modes of transportation) under USDOT, EUADR, IATA or IMDG regulations.

15. REGULATORY INFORMATION

Magnesium Stearate : Not listed

CERCLA/SARA 313 Emission reporting

California Proposition 65 : Not listed

Inventory-United States TSCA-Sect.8(b) : Present

Australia (AICS) : Present

EU EINE CS/ELNCS List : 209-150-3

Lactose NF, monohydrate

CERCLA/SARA 313 Emission reporting : Not listed



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California Proposition 65 : Not listed

Inventory-United States TSCA-Sect.8(b) : Present

Australia (AICS) : Not listed

Piroxicam

CERCLA/SARA 313 Emission reporting : Not listed

California Proposition 65 : Not listed

Australia (AICS) : Present

Standard for the uniform scheduling for drugs
and poisons : Schedule 4

EU EINE CS/ELNCS List : 252-974-3

Starch

CERCLA/SARA 313 Emission reporting : Not listed

California Proposition 65 : Not listed

Inventory-United States TSCA-Sect.8(b) : Present

Australia (AICS) : present

REACH-Annex IV- Exemptions from the
obligations of Register : Present

EU EINE CS/ELNCS List : 232-679-6

Hard gelation Capsules

CERCLA/SARA 313 Emission reporting : Not listed

California Proposition 65 : Not listed

EU EINE CS/ELNCS List : Not listed



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16. OTHER INFORMATION

Date of preparation: 06-Apr 2018

The information contained in this Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

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End of Safety Data Sheet